Part 113 – Medical - Round 2

COMMENT: One commenter requested the Office further define the term "paraphernalia."
RESPONSE: The Office acknowledges this comment and may consider including the definition in future guidance and rulemaking. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter requested clarification on whether the definition of "advertising" is inclusive of in-store collateral, giveaways, and messaging. The commenter stated that dispensaries provide information to customers that may not be disseminated in the traditional sense. The commenter further suggested that educational materials, in-store collateral, and/or giveaways that do not promote a specific cannabis product be excluded from the definition. The commenter stated that these types of materials do not constitute advertising in the conventional sense and the Office should not have the same interest in regulating such information the same way content is conveyed to the general public through websites, social media, brochures, print ads, TV, and other channels.
RESPONSE: The definition for "advertising" indicates disseminating communications in any manner or by any means, for the purpose of causing, directly, or indirectly, the purchase or use of a medical cannabis product brand or medical cannabis product. The Office acknowledges this comment; however, no changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested that the definition for "advertising" should include a warning that although state law authorizes the use of marijuana/cannabis for medical and recreational purposes, it still violates federal laws.
RESPONSE: The Office acknowledges this comment; however, no changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested that the references to stability testing be removed from the definitions "date of expiration or expiration date" and "use by date" or the Office of Cannabis Management (the Office) phase in the stability testing requirement to ensure adequate supply of products. The commenter stated that stability testing takes time to complete and to immediately require it would inhibit the introduction of new products and would be detrimental to patients. The commenter further suggested that the Office accept stability testing results from other medical and adult-use markets for products that are similar to products being offered by New York's medical program.
RESPONSE: For testing of open products, stability testing shall be performed at time zero when opened, and then, at a minimum, sixty (60) days from the date of first analysis. This shall establish use of the product within a specified time once opened. For testing of unopened products, until stability studies have been completed, a registered organization (RO) may assign a tentative expiration date based on available stability information. The RO must concurrently have stability studies conducted to determine the actual expiration date of an unopened product. No changes were made to the proposed regulations as a result of this comment.

COMMENT: Two commenters expressed concern about the lack of evidence supporting the effectiveness of medical cannabis use in the treatments for several of the listed conditions in section 113.1(k). One commenter suggested adding a requirement to inform patients that medical cannabis products have not been analyzed by the FDA and that there is limited information on the benefits of cannabis for treating a particular medical condition. Another commenter further suggested adding language to the safety insert

that indicates there is limited information on the benefits of using cannabis products to help treat approved medical conditions.
RESPONSE: Product labeling requires language be included stating "this product has not been analyzed by the FDA. There is limited information on the side effects of using this product and there may be associated health risks." No changes were made to the proposed regulations as a result of these comments.

COMMENT: Two commenters expressed concern about the last indication, "any other condition certified by the practitioner" in within the definition of "*Condition"* in section 113.1(k). One commenter stated that the inclusion of this indication allows for certification of conditions where evidence is unavailable to make informed decisions regarding risks and benefits of using medical cannabis. Another commenter stated that the last indication would make the preceding indications in the section meaningless. The commenter also suggested placing limits on the quantity of medical cannabis dispensed and on the time intervals between visits for reassessment. The commenter stated that the limits are needed due to ongoing concerns that cannabis is associated with a risk of unhealthy use and has an uncertain value in the treatment of several medical conditions.
RESPONSE: The Cannabis Law provides for certification for the medical use of cannabis for individuals under the care of a practitioner who determines the individual is likely to receive therapeutic or palliative benefits from cannabis. Certified patients may receive up to a sixty-day supply of medical cannabis at a time, and once the patient certification is made, follow-up care is at the discretion of the practitioner. Certifications may be made for up to one year, unless a patient is deemed terminally ill by the practitioner, whereby the certification has no expiration. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter expressed concerns about insufficient training being required to make recommendations regarding medical cannabis. The commenter stated that only two hours of training is not enough and that there is no reference in the regulations about ongoing continuing education, which is needed to stay current in a rapidly evolving field.
RESPONSE: Section 30(10) of Article 3 of the Cannabis Law provides that prior to issuing a certification a practitioner must complete, at a minimum, a two-hour course as determined by the board in regulation. This is the minimum requirement for practitioners to begin certifying medical patients. Other educational content, including but not limited to academic coursework, on-line courses and peer-reviewed journals are available to practitioners wishing to expand their cannabis knowledge base. The Office may consider ongoing continuing education requirements in future rulemaking. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested that requiring medical patients to be checked against the controlled substance database is stigma-building rather than being stigma-reducing. The commenter stated that this singles patients out as being less trustworthy than compared to the average person walking into an adult-use store who isn't being checked.
RESPONSE: Section 30(4) of Article 3 of the Cannabis Law provides that every practitioner shall consult the prescription monitoring program registry prior to making or issuing a certification, for the purpose of reviewing a patient's controlled substance history. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter requested guidance and clarification regarding the process for designating a caregiver facility. The commenter stated that the process incudes some unaddressed changes from the

previous DOH rules and would like to know if the Cannabis Data Management system can be used by patients to designate a caregiver facility or if there is a separate process that must be followed. The commenter also questioned if the patient needs to designate a caregiver facility first or does a facility need to be approved by the Office first. The commenter also stated that they are seeking to publish their own information memorandum as soon as the new regulations are adopted.

RESPONSE: A facility may apply to become an Office approved designated caregiver facility at any time without being designated as a caregiver by a certified patient. Detailed information about designated facility caregivers, including the designated facility caregiver registration form and frequently asked questions are available on the medical cannabis section of the Office website located here: https://cannabis.ny.gov/designated-caregivers. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested the Office should revise the reference to setbacks in the application under section 113.6(b)(2) to be consistent with the setback language in the general requirements under section 113.11(b). The commenter stated the Office indicated the new setback standard would be implemented consistently with existing medical regulations and the ABC law in that it would be measured in a straight line on the same avenue/street and not turn corners.

RESPONSE: The Office acknowledges this comment; however, no changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter requested clarification and flexibility on whether it is sufficient to submit financial statements for the ROs or "its parent company," rather than requiring NY-specific audited financials for renewal purposes. Additionally, the commenter suggested that the Office consider allowing flexibility for ROs to provide updates if things change or if projections are not met without such heavy enforcement.

RESPONSE: The Office will specify the acceptable types of financial documentation required for renewal at the time of application. An RO may change its composition, including but not limited to, a change in ownership, structure, or control, with notification to the Board and with prior written approval of the Board. No changes were made to the proposed regulations as a result of this comment.

COMMENT: A few commenters requested the Office require the terpene profiles to be included on the packaging and labeling in addition to the cannabinoid profiles. One commenter stated that patients require terpene profiles to know if a particular strain will be effective medicine for them. Another commenter stated that the state is lacking transparency with terpenes and certificates of analysis.

RESPONSE: The Office acknowledges these comments; however, no changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter suggested amending the medical cannabis product labeling prohibitions under section 113.12(m) and the prohibitions for marketing or advertising of medical cannabis products under section 113.17(b) to allow for the use of the term "organic" if the product is certified as organic or uses organic ingredients. The commenter stated that this change will ensure that products are not labeled as "organic" unless they truly qualify for that designation. Another commenter questioned why the Office prohibits the use of the term "organic" but not the use of the term "kosher." The commenter stated that their product containers are kosher certified and that it is entirely possible to produce organic cannabis without chemical pesticides and fertilizers. They also questioned if there will be a way for patients to determine if their medicine has been covered in chemicals.

RESPONSE: Section 34 of the Cannabis Law provides that an RO shall, based on the findings of an independent laboratory, provide documentation of the quality, safety and clinical strength of the medical cannabis manufactured or dispensed by the RO to the Office and to any person or entity to which the medical cannabis is sold or dispensed. No changes were made to the proposed regulations as a result of these comments.

COMMENT: Two commenters suggested the Office consider allowing certificates of analysis be made available to patients in other forms, such as paper, until the packaging and labeling requirements have been updated. One commenter stated that this information should be required to be made available upon request of the patient and shared in any suitable way. Additionally, the commenter indicated that the Office should require labs to implement a process to ensure the ability to share information via a QR code.

RESPONSE: Section 34 of the Cannabis Law provides that an RO shall, based on the findings of an independent laboratory, provide documentation of the quality, safety and clinical strength of the medical cannabis manufactured or dispensed by the RO to the Office and to any person or entity to which the medical cannabis is sold or dispensed. While a scannable bar code or QR code is preferred, an RO shall provide a physical or paper certificate of analysis directly to certified patients or their designated caregivers upon their request. No changes were made to the proposed regulations as a result of these comments.

COMMENT: Several commenters suggested adding a provision to medical cannabis product packaging minimum standards under section 113.12(j) to require cultivation centers to print a barcode or QR code of the BioTrack sublot number on each product label that leaves the facility. The commenters stated the BioTrack system automatically creates 16-digit sublot numbers that represent the unique shipping lots and that having this information in a form of a barcode or QR code will help identify each individual dispensary. The commenters also stated that this process is already standard practice in other states and that having this requirement will effectively combat diversion by making it easier for law enforcement to determine where in the supply chain a diversion occurred and also strengthen the market.

RESPONSE: Section 36 of the Cannabis Law requires ROs to adopt and maintain security, tracking, record keeping, record retention and surveillance systems, relating to all medical cannabis at every stage of acquiring, possession, manufacture, sale, delivery, transporting, distributing, or dispensing by the RO, subject to regulations of the Board. No changes were made to the proposed regulations as a result of these comments.

COMMENT: Two commenters suggested that the Office allow for an increase in the variety of cannabinoids available in cannabis products. One commenter stated that the regulations need to go past just THC and CBD in order to have the proper blend for maximum therapeutic effects and patient autonomy. Another commenter stated that the language regarding prohibitions on what medical cannabis products may contain in section 113.12(q) limits the range of products with minor cannabinoids that ROs can produce, indicating that cannabinoids, like CBN and CBG are often brought in from other suppliers to be more cost effective. The commenter also stated that products with these cannabinoids are important and popular for patients.

RESPONSE: Nothing prohibits an RO from including minor phytocannabinoids in their cannabis plants or in their cannabis products. ROs may not incorporate synthetic cannabis additives, artificially derived cannabinoids, or phytocannabinoids not produced by them by extraction, or obtained through a wholesale agreement with another RO, into final cannabis products as these additives may be of questionable quality and purity. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter suggested the language referencing the contact information for the Poison Control hotline be edited or removed from the regulations. The commenter stated that this language could imply that medical cannabis products are poisonous or dangerous.
RESPONSE: The Office acknowledges this comment; however, no changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested removing the definition for "synthetic terpenes" and the references to "synthetic terpenes", "flavors, or flavoring agents" from being prohibited in excipients and ingredients under section 113.12(c). The commenter stated that synthetic terpenes have the same molecular structure as those naturally occurring in cannabis and that the prohibition does not correspond to any clear public health outcome. The commenter also stated that the source of terpenes should have no bearing on the way they are regulated, indicating that sourcing terpenes from the plant is expensive and inefficient, and processors can easily isolate specific terpenes from hydrocarbon and botanical sources. Additionally, the commenter indicated that the section does not align with the guidance provided for Adult-Use Conditional Processors, which allow for the use of botanical terpenes in vaporization cartridges and single-use pens and without access to botanically derived terpenes, operators will struggle to bring their crops to market, find supply and be able to formulate products that patients desire.
RESPONSE Except for cannabis or hemp-derived terpenes, excipients and ingredients proposed for vaporized and inhaled medical cannabis products must be pharmaceutical grade unless otherwise approved by the Office. Botanical terpenes are not included in the list of prohibited excipients and ingredients and would be permitted if they were manufactured to a pharmaceutical grade, or otherwise approved by the Office. No changes were made to the proposed regulations.

COMMENT: One commenter suggested amending medical cannabis product packaging prohibitions undersection 113.12(k)(1) by removing the prohibition that packaging cannot have bright colors that are "neon" in appearance and to allow packaging with pictures, images, or graphics, other than what may be required, as long as such imagery is approved by the Office. The commenter stated by prohibiting the use of certain colors, it inhibits the operator's ability to create unique, compliant, adult-oriented packaging. The commenter also stated allowing additional imagery at the discretion of the Office would allow for operators to design a package in a manner that allows them to distinguish their products from other operators all while remaining complaint. Another commenter questioned if images of approved medical devices will be allowed to remain on existing packaging in the new regulations.
RESPONSE: The Office acknowledges these comments; however, no changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter requested clarification on whether marketing and advertising materials, including e-commerce materials, can feature packaging from other medical and adult-use markets as long as those marketing materials are consistent with the standards set forth by the Office. The commenter stated that allowing marketing and advertising to show out-of-state packaging would not be detrimental to the patients and would afford operators the ability to reduce costs, ultimately to the benefit of patients.
RESPONSE: Nothing prohibits ROs from featuring packaging from other medical markets in their marketing and advertising materials as long as they comply with the requirements set forth in Part 113, including any prohibitions. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested that ROs should not be limited to purchasing hemp from NY hemp producers. The commenter stated that it is a federally legal ingredient and if it is tested appropriately and grown under a legal state program, it should be permissible.
RESPONSE: ROs may purchase hemp extracts derived from hemp, processed, or manufactured in accordance with the Office's cannabinoid hemp program, and in accordance with applicable federal, state, and local laws and regulations. This includes the requirement that hemp processors maintain records of the out-of-state grower registration or license number in the respective jurisdiction. No changes were made to the proposed regulations as a result of this comment.

COMMENT: Two commenters suggested amending section 113.13(f) regarding purchase limits for medical patients. One commenter stated that restricting the amount of cannabis that can be purchased makes it harder for patients to get the medicine that they need. Another commenter stated that this requirement is over-engineering the patient-day supply that was enacted in the MRTA and to walk this back now will cause further confusion among patients.
RESPONSE: The purchase limits in Section 113.13 of this part are consistent with those set forth in Section 31 of the Cannabis Law. No changes were made to the proposed regulations as a result of these comments.

COMMENT: Two commenters suggested amending the requirements for dispensing sites under section 113.13 to authorize ROs the ability to sell medical cannabis wholesale to tribal nations such as the Shinnecock Nation, which have enacted medical cannabis laws and internal regulatory governance. One commenter stated that the tribal nation's cultivation and processing facility is ready to dispense medical cannabis to registered patients in coordination with multiple ROs that are willing to supply medical cannabis products.
RESPONSE: The Office acknowledges these comments; however, they are beyond the scope of the proposed regulations.

COMMENT: One commenter suggested that final product testing should be performed using validated methods, including those certified by the Association of Official Analytical Chemists (AOAC) Official Method of Analysis, Performance Tested Method and Reviewed and Recognized programs.
RESPONSE: The Office acknowledges this comment; however, it is beyond the scope of the proposed regulations.

COMMENT: One commenter suggested that the Office prioritize lab testing capacity for medical products prior to the launch of adult-use in order to protect and preserve supply for patients. The commenter stated that with only three labs within the state, the wait times for results are already long and will only continue to get longer once adult-use sends products for testing and patients should be prioritized.
RESPONSE: The Office acknowledges this comment; however, it is beyond the scope of the proposed regulations.

COMMENT: One commenter suggested that the Office base any unilateral modification of price per dose on transparent and verifiable data upon 30 days' notice to the RO.
RESPONSE: The Office acknowledges this comment; however, no changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested removing the term "marijuana" as an official word for cannabis from the marketing and advertising of medical cannabis under section 113.17. The commenter stated the term is racist and the use of it should be prohibited.
RESPONSE: The term "marijuana" was penned in Section 113.17 for its colloquial meaning. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter requested clarification on whether section 113.17(d)(1) regarding outdoor dispensing site signage is stating that ROs are permitted to have two outdoor signs per dispensing site rather than two outdoor signs in total for the RO license type.
RESPONSE: The Office acknowledges this comment and has made the clarifying change.

COMMENT: One commenter suggested that the Office allow reasonable adult-oriented promotions in the same manner that other industries are permitted to advertise. The commenter states that the restrictions in section 113.17(b)(23) regarding the marketing of free promotional items are overly restrictive and do not advance patient interests.
RESPONSE: Consistent with Cannabis Law, these regulations promulgate explicit rules prohibiting all marketing strategies and implementation including, but not limited to, branding, packaging, labeling, location of cannabis retailers, and advertisements that are designed to: appeal to persons less than twenty-one years of age and/or populations at-risk of increased adverse health consequences. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested amending section 113.17(a) regarding the general requirements for marketing and advertising. The commenter stated the addition of the "bright yellow" text box is not necessary to ensure that a warning is received and that a strong warning can still be provided without it. The commenter also suggested changing the reliable evidence percentage to 70% of the audience. They stated that the current percentage is overly restrictive compared to advertising restrictions in other medical cannabis markets and that making the change will ensure advertising is not directed at minors while also permitting reasonable advertising. The commenter further suggested removing the requirement that branded apparel only be sold within the licensed premises. The commenter stated that this restriction stifles the ability for licensees to build brands and that they should be able to sell apparel through electronic means, such as a website, which is properly age-rated and can ensure apparel is not being sold to minors.
RESPONSE: The Office acknowledges these comments; however, no changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter expressed concern that the revised regulations deleted a requirement from the medical cannabis marketing and advertising under section 113.17 that had been included in the earlier regulations to further protect the public from unsubstantiated advertising that would have required that any medical marijuana advertisement making any claims or statements regarding efficacy be submitted to the Office for review at least 60 days prior to dissemination. The commenter stated that pre-dissemination review of medical cannabis advertising is important for public protection and without this review and approval, vulnerable patients could be lulled into believing a product will ease their suffering with little data to support that claim. The commenter further suggested that section 113.17 be amended to re-include pre-publication review for any advertisement for a medical cannabis product claiming to be effective curing, treating, or preventing disease.
RESPONSE: Although pre-approvals were removed from section 113.17, the Office included significantly more detail about what types of advertising is and is not permitted in the regulations. ROs that do not

adhere to the regulations face strict violations and penalties. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter questioned what the prescription monitoring program registry is used for, how it is protected, and who has access to the information. The commenter stated adult-use will not be tracked like this and the new medical regulations punish patients and do not come close improving the program.
RESPONSE: Section 30(4) of Article 3 of the Cannabis Law provides that every practitioner shall consult the prescription monitoring program registry prior to making or issuing a certification, for the purpose of reviewing a patient's controlled substance history. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested that the references to the Public Health Law and the Vehicle and Traffic Law for the prohibition on the use of medical cannabis products in certain places in section 113.19 are incorrect. The commenter stated the reference to Public Health Law would be more appropriate if it referenced sections 1399-o and 1399-o-1 or if it referenced Article 13-E as an alternative. Additionally, they stated that the reference to Vehicle and Traffic Law would be more appropriate if it referenced section 125, which defines “motor vehicle” rather than section 129, which defines “park or parking”.
RESPONSE: Technical changes were made to section 113.19 as a result of this comment.

COMMENT: One commenter expressed concern about the reporting requirements for practitioners in section 113.20. The commenter stated that a practitioner may not be able to report to the Office the death of a patient or a change in status of a condition if the patient is only seen annually.
RESPONSE: A practitioner shall report to the Office, in a manner determined by the Office, the death of a certified patient for whom the practitioner has issued a certification not more than five (5) business days after the practitioner becomes aware of such fact. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested amending section 113.25(c) regarding the disposal of medical cannabis by deleting the requirement to weigh the disposed material. The commenter stated that some organic recycling facilities do not accept bagged waste, or cannabis waste, making the weight requirement impractical because you have to bag the waste in order to get the weight.
RESPONSE: The Office acknowledges this comment; however, no changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested removing the requirements of having the signatures of two staff members who witness the disposal and the process of anaerobic digestion. The commenter stated that anaerobic digestion is not possible and organic waste is biodegradable so it should be okay to have waste landfilled as long as it is rendered unusable.
RESPONSE: The Office acknowledges this comment; however, no changes were made to the proposed regulations as a result of this comment.

COMMENT: Several commenters requested the Office consider requiring a QR code be placed on the label of each product so patients can view the safety insert online. The commenters stated that to uphold a green initiative, the Office should require the safety insert be available online. They also stated that

mandating that a paper insert be provided for each product is wasteful and harmful to our environment and we should be working to reduce our carbon footprint.

RESPONSE: Pursuant to section 34(6) of the Cannabis Law, when an RO sells, delivers, distributes, or dispenses medical cannabis, it shall provide a safety insert. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter suggested revising section 113.26(c)(1) regarding dehumidifiers to include language referencing The U.S. Department of Energy's Appendix X1 to Subpart B of 10 CFR Part 430 to ensure consistency between federal and state regulations. The commenter stated that the section does not identify applicability to consumer or non-consumer products and does not provide a specific test method and incoming air conditions under which the minimum efficiency values are to be achieved.

RESPONSE: The Office acknowledges this comment; however, no changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter requested amending section 113.26(b)(1) regarding lighting standards to adopt a 1.9 PPE standard for lighting instead of 2.2 PPE. The commenter stated that adopting a 1.9 PPE standard would align with section 9 of the Office's guidance for adult-use conditional cultivators along with the standards set by other legal states.

RESPONSE: The Office acknowledges this comment and may consider it in future guidance and rulemaking. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter requested amending the energy and environmental section 113.26 to give ROs until January 1, 2025, to come into compliance with the current energy and efficiency standards and during the transition period, collect a report on the lights currently being used to assess their energy efficiency. The commenter stated that ROs utilize different types of lights for a variety of reasons and that the new standards are expensive and create a lot of uncertainty.

RESPONSE: The Office acknowledges this comment; however, no changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter requested further guidance from the Office on technical application of the language in section 113.26 (e.g., solid state lights are not LED, which are generally more energy efficient). The commenter stated that ROs utilize different types of lighting in different grow rooms for a variety of reasons and the Office should consult with a subject matter expert to further clarify this section before mandating certain lighting.

RESPONSE: The Office acknowledges this comment; however , no changes were made to the proposed regulations as a result of this comment.

COMMENT: Many commenters suggested that the Office provide a two-year grace period for ROs to become compliant with the revised packaging and labeling requirements in section 113.12 and to develop environmental sustainability and packaging programs. One commenter also suggested a grace period to phase out packaging made of single-use plastic, unless containing a minimum of 25% post-consumer content. The commenters stated that providing a grace period will provide time for ROs to develop and implement new packaging and labeling, use existing inventory and products to save money, carefully source packaging, and space to collaborate on programs that are sustainable and possible. Another commenter asked the Office to provide an exact date that an RO must comply with the new requirements.

RESPONSE: The Office acknowledges these comments and may consider them in future guidance and rulemaking. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter suggested implementing a license holder energy efficiency plan and energy data collection. The commenter stated that requiring a plan will help operators find ways to maximize energy efficiency while helping the state understand what market adoption is for different strategies. The commenter also stated that data collection will allow the state to create a baseline of energy consumption and greenhouse gas emission to help future goals in addition to data disclosures that will provide data to policymakers.
RESPONSE: ROs must provide annual benchmarking of energy and water usage, using either EPA Energy Portfolio Manager or the Resource Innovation Institute's Cannabis PowerScore, with the first report to be completed and submitted to the Office no later than one year after registration and with subsequent reports to be submitted annually to the Office thereafter. The Office may provide future guidance on a phased in approach for the energy and water usage. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter requested operators have access to energy efficiency incentives and rebates along with renewable energy sources. The commenter stated that having incentives and rebates are key to making innovative energy efficient technologies affordable and increasing market adoption. The commenter also requested the Office ensure that the standard does not create barriers to entry for regulated growers or undermine opportunities for utility incentives.
RESPONSE: The Office acknowledges this comment; however, it is beyond the scope of the proposed regulations.

COMMENT: One commenter suggested that the Office consult with other areas of the industry (e.g., product manufacturers and suppliers) for their expertise and establish an energy working group to educate state officials and other stakeholders on the latest energy efficient cannabis technology. The commenter stated that the energy policy must look holistically at operations to help reduce the carbon footprint.
RESPONSE: The Office acknowledges this comment; however, no changes were made to the proposed regulations as a result of this comment.

COMMENT: A few commenters questioned when the regulations will be approved and implemented.
RESPONSE: The Office must adhere to the New York State Administrative Procedure Act which governs the rulemaking process in New York State. The proposed regulations were posted on the Office webpage and published in the State Register on March 9, 2022, for the required initial 60-day public comment period, which ended on May 9, 2022. The Office reviewed the public comments received with this assessment of public comment and filed the proposed revised rulemaking, that was subjected to a 45-day public comment period, which ended on September 19, 2022. The Office reviewed the second round of public comments and does not intend to put the regulations out for additional revised rulemaking.

COMMENT: One commenter advocated to have pre-rolls added as a medical cannabis product. The commenter stated that there are many patients who can only absorb cannabinoids via smoking due to genetic disorders and by not allowing this product we are discriminating against patients in need as well as stigmatizing one type of product is better than another.

RESPONSE: Pre-rolls are an approved form of medical cannabis in New York. No changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter expressed their general support for the medical regulations. The commenter stated that they are very interested about learning the laws and regulations for both medical and adult-use regulations.
RESPONSE: The Office acknowledges this comment; however, no changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter urged the Office to reinstate the initial revision permitting remote pharmacist supervision. The commenter stated that having this operational flexibility is necessary due to the ongoing complications with the global pandemic and without it, the medical dispensaries in the state will have to continue to close when there is no pharmacist available in person. Additionally, having this revision would still mandate remote pharmacist supervision and only allow oversight at one dispensing location at a time which would preserve oversite and resources for patients.
RESPONSE: The Office acknowledges this comment; however, no changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter encouraged the Office to provide a definition of "unserved and underserved geographic areas" to implement the RO and dispensary expansion permitted by the Cannabis Law. The commenter stated that a definition is needed for the true expansion of the medical program.
RESPONSE: The Office acknowledges this comment; however, no changes were made to the proposed regulations as a result of this comment.

COMMENT: One commenter suggested that the Office issue a plan to award new ROs as mandated by the MRTA. The commenter also suggested that the Office provide clarity on its plan to issue additional medical licenses as well as the timing of the plan. The commenter stated that the medical cannabis program lacks diversity in ownership and that the state is overdue for a meaningful medical cannabis program that provides high quality and affordable cannabis.
RESPONSE: The Cannabis Control Board must consider, when deciding whether to grant a registration or amendment to a registration to an RO, among other things, whether the RO promotes racial, ethnic and gender diversity in their workforce. The plan and timing to consider additional ROs is beyond the scope of the proposed regulations.

COMMENT: Several comments were received regarding adverse events. Two commenters questioned how an RO will know about adverse events affecting certified patients and how ROs will inform patients about likely adverse events. One commenter stated that the safety insert only provides a warning and it would be more direct to provide information about likely adverse events and the known frequency that these events would occur. One commenter questioned how a practitioner will be able report serious adverse events to the Office within 5 days if the patient is only seen annually. Another commenter stated that having no specific monitoring requirements or recommended intervals for patients to follow-up with their practitioner during the one-year certification period, may be insufficient to detect adverse events that stem from cannabis use. They stated other controlled substances are monitored frequently allowing for assessment of benefits, and adverse events.
RESPONSE: Practitioners who certify patients for medical cannabis attest that they are caring for their patients which means, by definition in Cannabis Law, that the practitioner has completed a full assessment of the patient's medical history and current medical condition. Once the initial certification is completed,

follow up visits are at the discretion of the practitioner as well as at the request of a patient. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter suggested adding better warnings to multiple sections of the medical regulations. The commenter stated that patients, caregivers, medical providers, caregiver facilities, and ROs need to issue warnings about the risks associated with cannabis use for specific medical conditions indicated in section 113.1(k) and by not doing so, would be negligent because sick people will think cannabis is safe to use and they may be harmed. The commenter also stated that the warnings in section 113.12(l) and 113.17(a) are inadequate and cruel and that the Office needs to be more specific and forceful in the case of pregnant or nursing mothers and their children.
RESPONSE: The Office acknowledges these comments; and has continually strived to strike a balance between the compassionate provision of medical cannabis to patients with medical conditions while protecting public health and safety. The Office may consider these comments in future guidance and rulemaking. No changes were made to the proposed regulations as a result of these comments.

COMMENT: One commenter requested that the Office prioritize the review of medical product requests. The commenter stated that the Office is often unresponsive to requests, and it will be critical that these reviews are prioritized once the adult-use market is launched to protect patient access.
RESPONSE: The Office acknowledges this comment; however, it is beyond the scope of the proposed regulations.